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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/807,558	07/17/2001	Stefan Dietmar Anker	ICI 102	9145

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EXAMINER	
HAMUD, FOZIA M	
ART UNIT	PAPER NUMBER
1647	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/807,558	ANKER ET AL.	
	Examiner	Art Unit	
	Fozia M. Hamud	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,4,10,19-21 and 29-31* is/are pending in the application.

4a) Of the above claim(s) *20 and 21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3, 4, 10, 19, 29-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Response to Amendment

1a. Receipt of Applicant's amendment and arguments, filed on 30 October 2006 is acknowledged.

1b. Receipt of replacement drawings filed on 30 October 2006 is acknowledged.

Status of Claims:

1c. Claims 1, 3-4, 1, 19-21, 29-31 are pending, of which claims 1, 3-4. 10, 19, 29-31 are under consideration. Claims 21-22 stand withdrawn as being drawn to non-elected invention.

Response to Applicants' Amendment:

2. The following previous objections are withdrawn in light of Applicants amendments filed on 10/30/2007

(i) All of the r ejection of cancelled claim 2 is moot.

(ii) The rejection of claims 1-3, 19, 29-31 under 35 U.S.C. §112, first paragraph, for not providing enablement commensurate with the scope of the claimed invention is withdrawn. The claims are now drawn to a method of administering well known class of agents, i.e, beta blockers and aldosterone antagonists. Accordingly, the skilled artisan would be able to practice the claimed method.

(iii) The rejection of claims 1, 3, 19 made under 35 U.S.C. 112, first paragraph, for not complying with the written description provision of the statute is withdrawn, because the claims now recite well known agents.

(iv) The rejection of claims 1, 3-4, 19, 29-31 made under 35 U.S.C. 112, second paragraph, is withdrawn, because it is clear which sympathetic nervous activities would the recited beta blockers and aldosterone antagonists reduce.

(v) The objection to the specification made under 35 U.S.C. 132(a), is withdrawn in light of the decision of the Applicant' petition.

Claim rejections-35 USC § 102:

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 3, 4, 19, 29-31 stand rejected under 35 U.S.C § 102(b) as being anticipated by RALES investigators (October 1996), for reasons of record set forth in the office actions.

Applicants argue that the Examiner acknowledges that the RALES study did not select cachectic patients per se. Thus the Examiner concedes that RALES does not expressly disclose each and. every element of the claims because RALES fails to disclose a method to treat cachexia. Applicants submit that RALES discloses that some patients actually lost weight when treated with spironolactone. Thus is, contrary to the Examiner's position, RALES not only fails to disclose treating Cachexia. RALES discloses that treatment with 75 mg/d actually causes patients with chronic heart failure (but who do not necessarily have cachexia to lose weight. Applicants further argue that

the Examiner appears to suggest that RALES inherently discloses treating cachexia because some of patients were NYHA class II-IV. However, Applicants point out that it is important to not that not all patients with heart failure have cachexia. Applicants argue that the Courts of Appeals for the Federal Circuit Court has made it clear that a fact that a certain result or characteristic may be present in the prior art is not sufficient to establish inherency of the result or characteristic. Applicants submit that the Examiner's rationale is that some of the RALES patients might be cachectic, however, the Examiner has failed to show the patients in the RALES study were necessarily cachectic. Applicants argue that the mere fact that some of the patients were NYHA class II-IV, does not necessarily mean that the patients were cachectic. Applicants contend that NYHA classification is silent on the cachexia or weight loss.

These arguments have been considered, but are not deemed persuasive. The RALES study discloses a method of administering spironolactone to patients with severe congestive heart failure. Firstly, it is acknowledged that RALES study did not select cachetic patients per se. Secondly, it is acknowledged that not all patients with heart failure have cachexia and that the NYHA classification is silent on the cachexia or weight loss. Although the NYHA classification is silent on weight loss or cachexia, this classification was cited only to show that the patients in the RALES study suffered from severe heart failure as demonstrated by their classification as NYHA stages II-IV. Moreover, it is known in the art that cachexia is a common feature in patients with congestive heart failure, which may contribute to the poor prognosis of this disease, (see Freeman et al. Nutrition Reviews, Oct 1994. Vol.52, No.10, pages 340- 348).

Freeman et al disclose that congestive heart failure patients having NYHA classes III-IV, had 21% lower body weight compared to their normal counterparts, (see page 341, column 2). Therefore, one skilled in the art would conclude that some of the patients in the RALES study would be cachetic, since the study selected patients classified as NYHA classes II-IV.

Applicants' argument that in the RALES study treatment with 75 mg/d of spironolactone actually causes patients with chronic heart failure to lose weight, is not found persuasive, because, the instant claims do not recite specific doses, therefore, the claimed invention is not distinguished from the method disclosed by RALES. Furthermore, since a sub group of the RALES study patients are the same as the patients of the instant invention and since both patients are administered the same compound, manipulating the dosage does not make the instant method patentable over the prior art. Therefore, the RALES reference anticipates the instant claims 1, 3, 4, 19, 29-31. Claim 19 is anticipated by RALES, because, spironolactone affects kidney function which is a sympathetic nervous system activity.

New Rejection:

Claim rejections-35 USC § 102:

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 10, 19, 29-31 are rejected under 35 U.S.C § 102(b) as being anticipated by Packer et al, (New England Journal of Medicine, 1996. Vol. 334, pages 1349-1355).

The instant claims are drawn to a method of treating cahcexia in a patient by administering a beta blocker, (carvedilol) in an effective amount to reduce sympathetic nervous system activity,

Packer et al disclose a method of administering carvedilol (beta blocker) to chronic heart failure (NYHA stages II-IV) to assess the effect of carvedilol on mortality and cardiovascular morbidity in said patients, (see abstract). Packer et al disclose that fewer deaths occurred in the carvedilol group than in the placebo group and that hospitalizations occurred less frequently in patients allocated to carvedilol than in patients allocated to placebo, (see page 1351, column 1). Packer et al state that carvedilol is a sympathetic antagonist and conclude that Carvedilol was associated with reduced mortality and cardiovascular morbidity in patients with chronic heart failure, (see page 1349 and 1351, column 2).

Since a sub group of the patients treated by Packer et al would be cachectic, (see above), Packer et al reference anticipates the claimed method, because it discloses the administration of the same agent to the same patient population as the claimed invention.

Therefore, the Packer et al reference anticipates the instant claims 1, 10, 19, 29-31.

Conclusion:

5. No claim is allowed.

Advisory Information:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia M. Hamud whose telephone number is (571) 272-0884. The examiner can normally be reached on Monday, Thursday-Friday, 6:00 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda G. Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Fozia Hamud
Patent Examiner
Art Unit 1647
22 July 2006

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